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FROM: Mandy V. Wilson

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AUG 22 2005

Application No. 09/820,531
Reply to Office Action of June 20, 2005

IN THE U.S. PATENT AND TRADEMARK OFFICE

U.S. Patent Application S.N. 09/820,531

Title: MICROARRAYS TO SCREEN REGULATORY GENES
Inventor(s): E. Wang
Filed: March 29, 2001
Group Art Unit: 1634
Examiner: B. Sisson

CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via facsimile to Examiner Bradley L. Sisson, Group Art Unit 1634 of the United States Patent and Trademark Office, Alexandria, VA 22313 to centralized facsimile number (571)-273-8300, on Monday, August 22, 2005.
Name: Maddy Wilson
Signature: Maddy Wilson

REPLY PURSUANT TO 37 CFR 1.111

Commissioner of Patents
Alexandria, VA 22313-1450

Sir:

This Reply is being filed in response to the Office Action dated June 20, 2005. It is believed that no fee is due with this Amendment; however, if a fee is required, the Commissioner is hereby authorized to charge or credit Deposit Account No. 502752.

Issues under 35 U.S.C. 88 101 and 112

In the Office Action dated June 20, 2005, the Examiner rejected the pending claims under 25 U.S.C. §§ 101 and 112 using largely the same arguments supplied in the Office Action dated November 24, 2004. In making these rejections, the Examiner construed the claims "as encompassing one suspending time... air, light, any temperature, pressure, gravity, etc." and then argued that the claims-so-construed were not adequately described in the specification, were not enabled, and lacked utility.

In the response to the Office Action dated November 24, 2004, Applicant did not argue "that the interpretation of 'exogenous agent' was overly broad," as suggested in the Office Action dated June 20, 2005. Indeed, Applicant agrees with the Examiner in that "the art recognizes a tremendously broad array of exogenous agents as having, or potentially having an effect on genes of interest." In the response to the Office Action dated November 24, 2004, the Applicant submitted an argument that a reading of the language of the claims, given their ordinary meaning, would not involve the suspension of time or the blocking of any and all exogenous agents.

The meaning of the following claim language is at issue: "screening a sample microarray comprising genes ... exposed to the disease, age or exogenous agent ...; and comparing the

expression of the genes to expression of control genes ... not exposed to the disease, age or exogenous agent." The Examiner argues that this language encompasses suspending time and creating conditions to eliminate exposure to any and all exogenous agents, which impossible acts

2

construed, there would be no basis for any rejection contained in the Office Action. Applicant submits that the claim language does not encompass impossible acts such as suspending time or eliminating exposure of control genes to any and all exogenous agents.

Contemporaneously filed with this Amendment is a Declaration under 37 CFR 1.132 by Eugenia Wang, Ph.D., inventor of the present application, which provides support for the contention that one of ordinary skill in the art would not understand the claims to encompass suspending time or eliminating exposure to any and all exogenous agents.

It is respectfully submitted that one of ordinary skill in the art would understand that a "control" is designed and defined relative to another sample, to which it is compared. A control is never expected to be removed from the basic effects of the environment where scientific discovery takes place; rather, it is merely removed from the variable being tested, the variable in which the test sample is subjected. The claim language reasonably conveys to one of ordinary skill in the art that the "control genes" are "not exposed to the disease, age or exogenous agent" to which the genes of the sample microarray are exposed.

Because the claims do not encompass the ability to suspend time nor the ability to create conditions to eliminate exposure to any and all exogenous agents, the rejections pursuant to 35 U.S.C. §§ 101 and 112 are believed to be improper. It is further submitted that the method of the present invention is useful because it identifies characteristics in samples of interest by comparing previously defined information for multiple samples to one another. For example, the characteristics identified through the method of the present invention for samples of interest may include a hierarchical order of genes and/or losses of a particular gene or a group of genes,

3

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Application No. 09/820,531
Reply to Office Action of June 20, 2005

relative to the other samples. Changes in gene expression have been found to correlate with diseases or disorders and identification of such changes allow for diagnosis and assessment of potential treatments. See e.g., US Application Publication 2002/0009736, Paragraphs [0061] [0073].

In light of the foregoing remarks and the Declaration submitted herewith, Applicant respectfully requests allowance of all claims now pending in this Application.

Respectfully submitted,



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